

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
5 April 2001 (05.04.2001)

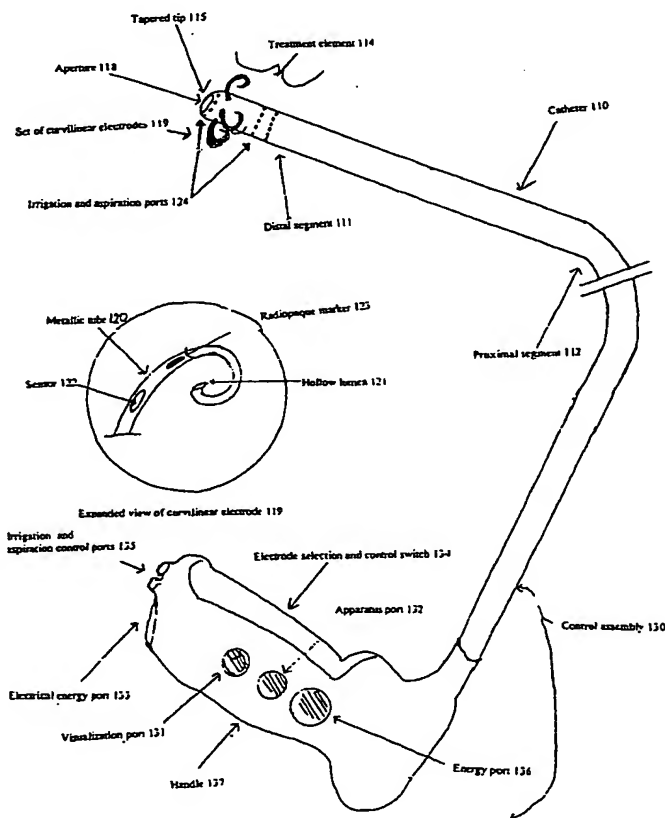
PCT

(10) International Publication Number
WO 01/22897 A1

- (51) International Patent Classification⁷: A61B 18/18, (72) Inventor: EDWARDS, Stuart, D.; 658 Westridge Drive, A61N 5/02, 5/06, 7/02 Portola Valley, CA 94028 (US).
- (21) International Application Number: PCT/US00/26831 (74) Agent: SWERNOFSKY, Steven, A.; Swernofsky Law Group, P.O. Box 390013, Mountain View, CA 94039-0013 (US).
- (22) International Filing Date: 28 September 2000 (28.09.2000) (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: 09/407,658 28 September 1999 (28.09.1999) US (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
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(54) Title: TREATMENT OF TISSUE BY APPLICATION OF ENERGY AND DRUGS



(57) Abstract: The invention provides a method and system for treating disorders parts of the body. A particular treatment can include one or more of, or some combination of ablation, nerve modulation, three-dimensional tissue shaping, drug delivery, mapping, stimulating, shrinking and reducing strain on structures by altering the geometry thereof and providing bulk to particularly defined regions. The particular body structures or tissues can include one or more of, or some combination of reions, including the bladder, esophagus, vagina, penis, laryns, pharynx, aortic arch, abdominal aorta, thoracic aorta, large intestine, small intestine, sinus, auditory canal, uterus, vas deferens, trachea and all associated sphincters. Types of energy that can be applied include radiofrequency, laser, microwave, infrared waves, ultrasound or some combination thereof. Types of substances that can be applied include pharmaceutical agents such as analgesics, antibiotics and anti-inflammatory drugs, bulking agents such as biologically nonreactive particles, cooling fluids or dessicants such as liquid nitrogen for use in cryo-based treatments.

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mapping and modulating nervous pathways responsible for urinary urgency, (4) reducing strain on the bladderneck by changing the structural geometry, (5) shrinking discrete and non-discrete areas of the bladder by creating thermal lesions, (6) three-dimensional modeling of tissue by adding bulk so as to achieve better closure (7) strengthening the structural integrity of a tissue by providing a pattern of scar tissue and (7) application of pharmaceutical agents both as a curative and to promote healing post treatment.

The use of a catheter to apply radio frequency (RF) and other types of energy to ablate tissue in the body (such as heart muscle tissue) is known in the art of cardiac treatment. However, known systems using RF and other types of energy are still subject to several drawbacks.

A first problem in the known art involves providing a device that can perform all of the aforementioned functions. While known systems can perform one or more of these functions, nothing in the related art is capable of performing all of these functions. Patients are frequently required to return for multiple treatments until a cure is finally effected.

A second problem in the known art involves identification, modulation and/or stimulation of nerves in the targeted tissue. Known systems do not provide for protection of sensitive nerves during treatment or allow nerves to be identified and stimulated. This is particularly problematic because many tissue disorders, especially those involving tone or contractile ability of a sphincter, arise from afferent and efferent nerves are either under-stimulated or over-stimulated.

A third problem in the known art involves providing a treatment surface that can reach all of the desired treatment areas, such as the entire surface of the detrusor muscles. While the use of a catheter to deploy energy is known, none is disposed to flexibly adapt to the interior shape of an organ so as to provide optimal uniform treatment.

A fourth problem in the known art involves removal of tissue and substances used in treatment. Known systems do not provide for removal of excess substances used in treatment such as cooling fluids, collagen or bulking substances. Similarly, known systems do not provide for removal of substances that hinders or otherwise obstructs the healing process such as pus, purulent discharges, suppuration and pockets of infection.

A fifth problem in the known art involves directing and positioning the electrodes in the body cavity or orifice. Difficulties in accurately positioning the electrodes in the target orifice detract from treatment. Frequently, unhealthy tissue remains untreated while healthy tissue is compromised. Difficulties in directing and positioning the electrodes are particularly problematic because one of the goals of treatment is to minimize collateral damage to healthy tissue and to completely treat diseased tissue.

A sixth problem in the known art involves minimizing thermal injury to the patient. Some known systems rely upon simultaneous application of energy and infusion of a cooling liquid into the targeted area for treatment. While such infusion of liquid minimizes thermal injury to the patient, it is not applicable to all parts of the body. For example, infusion of cooling liquids into an internal body cavity such as a bladder, uterus, or stomach can rupture the targeted organ or cause osmotic imbalance within the tissue.

A seventh problem in the known art involves difficulty in the simultaneous use of complimentary technology. Known systems do not provide for optimal, simultaneous use of auxiliary tools for visualization, monitoring pH and pressure or drug administration.

A eighth problem in the known art is that it can be difficult to block the flow of bodily fluids and gases into an area of the body where tissue ablation is taking

place. Bodily fluids can dissipate and detrimentally absorb the energy to be applied to the tissue to be ablated. Dissipation of bodily fluids detracts from the goal of treatment of diseased tissue.

5 Accordingly, it would be advantageous to provide a method and apparatus for treatment for body structures, especially internal body structures involving unwanted features or other disorders, that does not require relatively invasive surgery, and is not subject to other drawbacks noted with regard to the known art. This advantage is achieved in an embodiment of the invention in which a
10 relatively minimally invasive catheter is inserted into the body, a variety of different treatments of the body structures is applied using electrodes and a cooling element, and the unwanted features or disorders are relatively cured.

Summary of the Invention

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The invention provides a method and system for treating disorders of the genito-urinary tract and other disorders in other parts of the body. A particular treatment can include one or more of, or some combination of ablation, nerve modulation, three-dimensional tissue shaping, drug delivery, mapping, stimulating,
20 shrinking (by creation of a pattern of thermal lesions) and reducing strain on structures by altering the geometry thereof and providing bulk to particularly defined regions.

The particular body structures or tissues can include one or more of, or
25 some combination of regions, including the bladder, esophagus, vagina, penis, larynx, pharynx, aortic arch, abdominal aorta, thoracic aorta, large intestine, small intestine, sinus, auditory canal, uterus, vas deferens, trachea and all associated sphincters.

In one aspect of the invention, a catheter is deployed in the body. It
30 may enter the body via a natural orifice, a stoma, or a surgically created opening that

is made for the purpose of inserting the catheter. Insertion may be facilitated with the use of a guide wire or a generic support structure or visualization apparatus.

5 In second aspect of the invention, the treatment can include application of energy and substances to effect changes in the target tissue. Types of energy that can be applied include radiofrequency, laser, microwave, infrared waves, ultrasound or some combination thereof. Types of substances that can be applied include pharmaceutical agents such as analgesics, antibiotics and anti-inflammatory drugs, bulking agents such as biologically nonreactive particles, cooling fluids or dessicants
10 such as liquid nitrogen for use in cryo-based treatments.

Brief Description of the Drawings

Figure 1 is a block drawing of a system for treatment of female urinary
15 incontinence using a first device.

Figure 2 is a process flow drawing of a method for treatment of female urinary incontinence using a first device.

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Figure 3 is a block drawing of a system for treatment of female urinary incontinence using a second device.

Figure 4 is a process flow drawing of a method for treatment of female
25 urinary incontinence using a second device.

Figure 5 is a block drawing of a system for treatment of female urinary incontinence using a third device.

30 Figure 6 is a flow drawing of a method for treatment of female urinary incontinence using a third device.

In a step 612, electrodes 522 are selected using the electrode selection and control switch 534. In a preferred embodiment, all electrodes are selected. In another embodiment, individual electrodes may be deployed.

5

In a step 613, individual nerves within the bladder are identified using sensors 526. This step is optional.

In a step 614, the therapeutic energy port 536 is manipulated so as to cause a release of energy from the electrodes 522. The duration and frequency of energy are responsive to judgments by medical personnel. This release of energy creates a pattern of lesions in the mucosal and/or submucosal tissues of the bladder or portions thereof. The affected area shrinks and is relatively strengthened, so as to better retain urine.

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In a step 615, the therapeutic energy port 536 is manipulated so as to cause a release of energy from the electrodes 522 that is directed at the nerves that were identified in step 613. Manipulation and modulation of these nerves may directly or indirectly affect incontinence related to an uncontrolled urge to urinate.

20 This step is optional.

In a step 616, bulking agents such as organic microspheres, collagens, silicone, PVC and other organic breathable and unbreathable polymers are exuded from selected electrodes 522 into tissues near the base of the bladder. The type of microspheres and bulking substances and the locations where they are exuded are responsive to judgment by medical personnel. These bulking agents can be used to strengthen these structures so as to prevent incontinence caused by stress. This step is optional.

30

In a step 617, pharmaceutical agents may be locally administered by manipulating the irrigation and aspiration control ports 535. These agents may help

Generality of the Invention

The invention has substantial generality of application to various fields for biopsy or treatment of medical conditions. These various fields include, one or
5 more of, or a combination of, any of the following (or any related fields):

As noted above, the invention can be used in any area of the body, including the biologic systems and locations noted herein. The invention can be used for the general purpose of reducing, plumping, or reshaping body structures, tissues,
10 or regions of the body otherwise empty (or filled with biologic substances).

For examples, the invention can be used in one or more of, or some combination of, the following:

- 15 o In the head and neck, such as the cheeks, eyes, sinuses, middle ear, nostrils, inner ear, Eustachian tubes, pharynx, larynx, or other structures;
 - o For the purpose of reforming damaged body parts, for the purpose of reshaping misshapen body parts, dilating occluded tissues, or for cosmetic
20 effects;
- or
- For the purpose of replacing the volume filled by body parts that are missing, whether due to congenital defect, infection, or surgery.

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Alternative Embodiments

Although preferred embodiments are disclosed herein, many variations are possible which remain within the concept, scope, and spirit of the invention, and
30 these variations would become clear to those skilled in the art after perusal of this application.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU03/01359

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. 7: A61N 7/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI; IPC: A61H, A61B, A61N; Keywords: Vibrat+, oscillat+, reflex, involuntary, cough, spasm, neck, throat, pharynx, larynx, ultraso+

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	Derwent Abstract Accession No. 2003-604797/57, Class P33; S05, RU 2208429 C2 (OMSK AVTOMATIKA WKS STOCK CO) 20 July 2003	1, 9
X	WO 200122897 A1 (NOVASYS MEDICAL INC) 5 April 2001 See abstract; page 4, line 16 - page 5, line 10; page 36, lines 15-16	1, 9

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
10 December 2003

Date of mailing of the international search report
18 DEC 2003

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